United States Court of Appeals

for the Second Circuit

APPELLANT'S REPLY BRIEF

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P/S

74-1999

To be argued by
COPAL MINTZ

United States Court of Appeals

FOR THE SECOND CIRCUIT

No. 74-1999

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

—against—

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation,
Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

DEFENDANT-APPELLANT'S REPLY BRIEF

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DEFENDANT-APPELLANT'S REPLY BRIEF

I

THE GOVERNMENT'S LEGAL ARGUMENTS HAVE NO APPLICATION TO THE FACTS AND CIRCUMSTANCES OF THIS CASE

The government, if appellant's counsel correctly understands the government's brief, justifies Judge Dooling's

superseding of Judge Rosling's earlier "Permanent Injunction" under the Federal, Food, Drug, and Cosmetic Act, on the ground that it is a "more comprehensive and specific" carrying into effect of "the purpose" of the earlier Permanent Injunction. As such, the government argues, the superseding is sanctioned - contrary "to the rules as pertain to ~~provide~~ PRIVATE litigation" - as a "statutory injunction" (Appee's Br. pp. 1, 7-8). Thus, the government seems to argue that the relevant Federal Rules of Civil Procedure do not apply, nor does the due process requirement of secundum allegata et probata.

Before discussing the legal tenability of that thesis, we turn first to the cited statute to examine what it actually provides in regard to injunctive relief. Then we compare therewith the complaint against defendant-appellant to determine the purposes thereof. Then we turn to Judge Rosling's judgment which this court affirmed to see if it was wanting in any respect.

The Statute

The pertinent provision of the Federal Food, Drug and Cosmetic Act is Section 332(a), the pertinent part of which, reads (see Applt's. Br., p. 19):

"(a) The district courts of the United States . . . shall have jurisdiction, for cause shown, to restrain violations of Section 331."

Section 331, in pertinent parts, (see Applt's. Br., p. 19), under the title "Prohibited acts", prohibits the doing of or causing:

"(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded".

* * *

"(k)" tampering with "the labelling of, or the doing of any act with respect to, a . . . device, . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded".

Since adulteration is not involved here, we are concerned only with misbranding.

Thus, as far as the statute goes and applies, it provides only for the restraining of (i) the introduction or delivery for introduction into interstate commerce of devices that are misbranded and (ii) the misbranding of devices while held for sale after shipment in interstate commerce.

The Complaint

The complaint[1] (summarized by Judge Rosling at

1 Reproduced in full at pages 13a-31a in Vol. 1 of the Appendix in prior appeals No. 72-2128 and 73-1342 from Judge Rosling's judgment.

20A-24A)[2] identified the action as brought under the Federal Food, Drug and Cosmetic Act, Section 332(a) of 21 U.S.C., to restrain violations of Sections 301(a) and (k). It complained of the labelling (21A-22A) of "a device" designated "Diapulse", which was described as "a pulsed electromagnetic generator which resembles a conventional diathermy unit but lacks the energy output of conventional medical diathermy units" and "purports", unlike the latter, to achieve therapeutic results without generating heat" (Paragraphs 3 and 4 of the complaint, paraphrased at 20A; emphasis added). The complaint referred to the Connecticut litigation (22A) and alleged that notwithstanding the adjudication therein, the defendant, in Judge Rosling's words, "has not corrected or repudiated any of[its] claims or representations, but continues to make and use them" (22A).

By way of relief, the complaint prayed that the defendant and its officers, etc., "be perpetually enjoined under 22 U.S.C. 332(a) from causing said Diapulse device or any similar device to be introduced or delivered for introduction into interstate commerce" and from doing any act in violation of 21 U.S.C. 331(k) "which causes said Diapulse device or any similar device to become misbranded while held for sale after shipment in interstate commerce". [Emphasis added]. The complaint prayed further that the defendant be

[2] Numerals followed by the letter "A", except when otherwise indicated, refer to page numbers of the Appellant's Appendix.

enjoined from introducing or delivering for introduction into interstate commerce of "said device or any similar device with any claims whatever . . . unless and until" FDA approves the labelling thereof (pp. 17a-18a of the Appendix in the above referred to prior appeals, summarized at 23A-24A).

Judge Rosling's 1972 Permanent Injunction

Following a decision which meticulously recited the entire history of FDA's litigation against the defendant since 1965 (including all of the decisions) and summarized the allegations against defendant and set forth his findings thereon (19A-60A), Judge Rosling entered, on July 18, 1972, a "Permanent Injunction" which, comprehensively and meticulously, embodied all of the relief prayed for in the complaint. That included a complete ban of interstate marketing of Diapulse or any similar modality unless and until FDA approved the labelling thereof.

There is no claim that the 1972 "Permanent Injunction" was (or is) deficient in any respect. It left out nothing that has been thought of since in regard to the subject of the action, i.e., the athermal device Diapulse with the athermal therapeutic claims for it.

Nor is there any claim that since the entry of the 1972 "Permanent Injunction" - nor since the entry of Judge Rosling's temporary injunction of December 8, 1971 - there

has been any marketing of the Diapulse or of any similitude of it or any distribution of athermal labelling.

The Contempt Proceeding

The controversy engendered by the criminal contempt proceeding, commenced in August 1973, was not for alleged perseverance in marketing an athermal device or in continuing athermal therapeutic claims.

Directly to the contrary, the subject of the proceeding was defendant's endeavors to enable possessors of Diapulses to convert them (or have them converted) to thermal diathermy devices with very limited claims of therapeutic capability, all of them well within their ranges of heat.

To that end, defendant assembled kits of standard electro~~magnetic~~ N/C parts to effect such conversion by substantially increasing the average as well as peak wattage, adding new settings and increasing the rates of pulsation (76A-79A). With the contents of those kits, the maximum peak power was increased from 945 to 2,153 watts (76A), the maximum average watts of power was increased from 38 watts (96A) to 137 watts (98A), the capability of raising tissue temperature was increased from 101-1/2°F (69A) to 104°F (81A), the latter being sufficient for "mild temperature heat therapy" (96A).

With the kits were distributed a 4-page P/EmF brochure "phrased exclusively in terms of heat treatment" (81A).

That brochure made "it plain . . . that the converted unit will produce only enough heat to raise the temperature of deep muscle tissue 2 inches below the mid-thigh from 98.6°F, to 104°F, in an average time of less than 15 minutes with the switch in 'up' position and both the penetration and pulse frequency to the highest setting of 12 and 6" (81A).

Accordingly, the brochure made only 9 claims (83A) - in marked contrast to even the partial list, at page 87A, of conditions for which diathermy is recognized as useful therapy - and directly under the table of those 9 physical conditions for which the apparatus may be used, appeared the statement (81A):

> "The beneficial effects of diathermy are derived solely on the basis of heat produced."

Directly under the listing of the "Operating Procedures", the brochure, in reference to the lower settings of 1-6, said (81A):

> "Note: The FDA and many medical authorities are of the opinion that these lower settings are medically useless" (85A). [3]

There is no finding - reflecting, it must be assumed, the absence of evidence - that in generally accepted diathermy practice, the 104°F limit is not the proper dosage for the 9 specified conditions nor that greater heat is not contra-indicated.

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3 All of the foregoing references 76A et seq. are to Judge Dooling's Memorandum and Findings (65A-103A).

Thus there is no finding and there is no evidence that the projected P/EmF was in any way misbranded by the 4-page brochure or otherwise. Therefore, the P/EmF kits were not devices that had been complained of in the complaint or were barred by the 1972 "Permanent Injunction". Moreover, there is no proof or finding that the introduction into interstate commerce of P/EmF or its parts with the 4-page brochure would be a violation of Sections 331(a) or 331(k) of 21 U.S.C.; that is necessarily so in the absence of proof or finding of falsities in that brochure.

Consequently, the dismissal of the contempt proceeding should have forestalled a quest for restraints beyond and in addition to those contained in the 1972 "Permanent Injunction", even if power existed to so modify that final judgment.

The state of the record is not altered by Judge Dooling's conclusion (94A) that the P/EmF activities "constituted an evasion and not avoidance of the strictures of the permanent injunction and its purpose". It is a truism that an injunction does not operate beyond its terms. Nothing is proscribed by an injunction that is not comprehended by its terms and is within its stated scope. The subject of the action and of the injunction was an athermal device

represented to have therapeutic capabilities of - indeed superior to - conventional diathermy, which FDA deemed false and hence misbranding. That is made clear by Judge Dooling himself by the following at 70A:

> "The Diapulse was over the years presented aggressively as an electromagnetic therapeutic device. It was, explicitly, not for heat therapy . . . The insistence of defendant Ross and the corporations for which he speaks continues to be on the validity and utility of the use of pulsed, short-wave, high peak-power, electromagnetic induction as a therapeutic agent, . . .".

The sanctions that were sought by the complaint were not to outlaw the device Diapulse, but to enjoin the labelling which was deemed false; and to that end defendant was prohibited from transporting interstate any Diapulse unless and until FDA approved the labelling thereof.

Notwithstanding defendant's deep faith referred to by Judge Dooling (a faith which, perhaps, soon will be vindicated), defendant, in obedience to the September 8, 1971 preliminary injunction (17A-18A) and the July 18, 1972 superseding "Permanent Injunction", completely ceased and desisted from interstate marketing of Diapulse and completely ceased and desisted from propagating, commercially, its deeply embedded faith.

Therefore, the evasion-avoidance dichotomy, whatever may be its theoretical applicability, was and is devoid of factual application to this case.

In any event, the 1972 "Permanent Injunction" needed no improvement in effectively and completely barring Diapulse and its labelling.

The Different Target of the 1974 Superseding Permanent Injunction

(1). Thus, the primary subject of the 1974 Permanent Injunction is something other than Diapulse which already was effectively barred. That subject (as appears at pages 6 - 7 of Defendant-Appellant's brief and at 106A-112A, 116A-117A, 123A-124A) is the marketing by defendant of high frequency pulsed diathermy devices which - unlike the Diapulse device and beyond the capabilities of P/EmF - heat tissue to the 113°F upper limit of conventional diathermy (127A) - devices which, with FDA acquiescence, other manufacturers and distributors freely market and do so with the same prolific therapeutic claims that are standard for conventional diathermy devices (see partial list at 87A; cf. 90A).

When Judge Dooling proposed that peak power be barred (restriction (a) at 98A), defendant objected thereto (107A-112A) and the Government embraced it (116A-117A). In support of its objection, defendant argued to the court inter alia (108A):

> "That limitation is unnecessary since [Judge Dooling held in his decision of May 7, 1974] 'average wattage' is the governing factor and

> the required average wattage is assured by the [heat] requirements . . . If the reason for the limitation be an apprehension that therapists may prefer a modality with a high rate of pulsation in the belief that even though there is no accepted scientific evidence that the pulsation has any therapeutic effect, nothing is lost from the pulsation and something may be gained, we ask: what objection can there be to action on that basis if the therapist chooses to so act, what harm comes therefrom?"

(2). As pointed out in Appellant's Brief at pages 7-14 and pages 42-47, the 1974 "Permanent Injunction" contains six other drastic provisions not contained in the 1972 judgment most of which find no justification in 22 U.S.C. 331(a), 331(k) and 332(a). Since those are fully discussed in Defendant-Appellant's main brief (at pp. 5-10 and 42-47), we add only several brief comments (at pages 15-17 infra.).

We welcome being corrected (at p. 17 of Appee's Br.) that the "recall" provision applies only to P/EmF's and to Diapulses which were converted into P/EmF's of which there may be 300 or so. That limitation, however, does not validate the requirement (see further p. 17 infra.).

Palpably erroneous is the government's assertion (at p. 6 of its brief) that "Judge Dooling had found the P/EmF "both in law and in fact the same as Diapulse (79A)". Neither at referred to page 79A (which must be read with 80A) or elsewhere is there such a finding. Directly to the contrary are: (i) the dismissal of the contempt proceeding, (ii) the

4-page brochure which accompanied the P/EmF kits, (iii) the absence of a finding or suggestion of any fault with the contents of that brochure, (iv) the entire tenor of Judge Dooling's exposition not that the P/EmF is not different from Diapulse but that therapists could, if so minded, use the P/EmF "with minimal increase in tissue temperature as electromagnetic therapy accompanied by some unavoidable but unsought for increase in tissue temperature" (95A; emphasis added).

Manifestly, an instrument with two or more capabilities is not the same as an instrument with only one of them. They do not become the same because it is possible for a user thereof to choose to utilize, contrary to specific instruction, only one of the attributes of the device. A drug is not the same as a placebo because, if used minimally in disregard of the dosage necessary for effectiveness, it has no therapeutic effect.

II

THE GOVERNMENT'S LEGAL ARGUMENTS ARE UNTENABLE

(1). We submit that the citations and quotations in Defendant-Appellant's brief demonstrate conclusively that the Federal courts do not possess any "inherent power" to change the provisions of final judgments.

The phrase "inherent power" does not appear in United States v. United Shoe Machinery Corp., 361 U.S. 244 (1968). That decision established the proposition that in a complex anti-trust case where the complaint seeks the effective

charged pervasive monopoly and the court,
t the charged monopoly exists, in an endeavor
a competitive market, fashions a complex
an that proposed by the Government) with a
g for reports and a judicial review ten years
and to what extent the directed measures
reed result - in such circumstances the decree
additional or different directions when it
se contained in the original decree failed to
eed result. The decree in that case also
ction to consider "at any time" applications
r orders and directions as may be appropriate
on, construction, or carrying out of this Decree,
the Decree and to take further proceedings if
its justify that course in the appropriate
he Anti-Trust Act" (Footnote 3 on p. 250).
he shoe machinery company appealed that Decree,
was informed that the District Court had
premise that relatively mild remedies should
rst resolution and that the possibility of more
should be held in abeyance". "Paragraph 18
he Supreme Court said, "appeared to be in
his statement since it expressly required a
ears of experience under the Decree and
petitions for modifications might be filed

'in view of [the de
competition'" (at p

Consequent
decree had failed "t
petitioned for relie
Court held that the
whether the relief i
this court has presc
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. . . ."

What is sa
inapplicability of t
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calls for a complexi
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Therefore,
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was shown that the de
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have been the duty of
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cree's] effect in establishing workable
. 249).

tly, when the Government asserted that the
to recreate a competitive market" and
ef to effect that purpose, the Supreme
district court "should proceed to determine
n this case has met the standards which
ribed. If it has not, the district court
cree so as to achieve the required result

id at pages 1-12 supra demonstrates the
nat decision to the case at bar. That
y where the statutorally mandated objective
ty of relief evolvable only by trial and
e a decree must necessarily remain open,
ecree contains express reservations, for
ed remedies which fail to achieve the

even if the 10-year provision were not
preme Court said, "if after 10 years it
cree had not achieved the adequate relief
nt is entitled in a §2 case, it would
the court to modify the decree so as to
xtirpation of the illegal monopoly . . .

Its duty is implicit in the finding of the violations of §2 and in the decisions of this Court as to the type of remedy which must be prescribed" (at p. 251).

The demarcation between United States v. United Shoe Corp. and this case is that in a complex case under the Anti-Trust statutes which call for the eradication of a complex monopoly, a trial and error decree is essentially, and as a matter of law, interlocutory - although that term does not appear in the decision - until the extirpation is complete. The interlocutory nature is "implicit" in the court's duty under the statute.

Nothing of that character is suggested by or in the very limited provisions in sections 331(a) and (k) and 332(a) of the Federal Food, Drug, and Cosmetic Act.

(2). As in United States v. Swift & Co., 286 U. S. 106 (1932), the cases cited by the government as supporting the superseding of the 1972 Permanent Injunction - System Federation v. Wright, 364 U. S. 624 (1961), Ridley v. Phillips Petroleum Co., 427 F 2d 19 (10 Cir., 1970), King-Seeley Thermos Co. v. Aladdin Industries, Inc., 418 F 2d 31 (2 Cir., 1969), Securities and Exchange Commission v. Thermodynamics Inc., 464 F 2d 457 (10 Cir., 1972), were all applications for relief from injunctions. In two of them, the applications were denied and such denial was affirmed. In System Federation, the denial was reversed by the Supreme Court. In King-Seeley

Thermos Co. v. Aladdin Industries, Inc., the denial of the application was remanded by this Court for further consideration.

To those cases can be added Schildhaus v. Moe, 335 F 2d 529 (2d Cir., 1964), and Humble Oil and Refining Co. v. American Oil Co., 405 F 2d 803 (8th Cir., 1969). Each of them was an application for relief from an injunction. In Schildhaus, the vacatur of an injunction was reversed by this Court. In Humble Oil, the denial of the application was affirmed.

In Doe v. Hodgson, decided by this Court July 22, 1974 (Apee's Br. p. 12), we find nothing relevant.

(3). On the issue of whether a device owned by a therapist for use by him in treating patients is "held for sale", of the cases cited by the Government (on p. 20 of its brief): Hipolite Egg Co. v. United States, 220 U.S. 45 (1911), held that ingredients in the possession of a baker for inclusion in baked goods to be sold by him are included in the concept of "held for sale". In United States v. Kocmond , 200 F 2d 370 (7th Cir., 1952), it was not disputed that the horsemeat there involved was "for sale" in the commercial sense of the word. In United States v. Ten Cartons . . . Hoxsey Tablets, 152 F. Supp. 360, the tablets and medications, were, pursuant to doctor's prescriptions, handed over to patients at the drug

counter of the clinic and were taken home for consumption according to given directions. Manifestly, none of those cases is in point. United States v. an Article of Device . . . Cameron Spitler, 261 F Supp., 243 supports the Government's position. That lone decision by a District Court in Nebraska, stretching a phrase beyond its normal connotation, we respectfully suggest, is hardly persuasive authority.

(4). In respect to the access and inspection provisions, the cases cited by the Government (at p. 23 of its brief) were actions to restrain violations of the statute in the process of manufacturing drugs; in one case it was a "new drug". In such cases access and inspection to verify compliance are reasonable to the extent provided for in section 374 of the Act. Those cases have no application here.

(5). In respect to "recall", the cases cited by the Government (at p. 22 of its brief) all involved drugs which were contaminated or otherwise dangerous to health.

Respectfully submitted,

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November 11, 1974